

Serial No.: 10/801,307
Examiner: Jason J. Boeckmann
Group Art Unit: 3752

IN THE DRAWINGS:

Please replace Figures 1-8 with amended Figures 1-8, as provided on eight (8) replacement sheets. As amended, Figures 1 through 8 now contain the label, PRIOR ART.

Please replace Figure 11 with amended Figure 11, as provided on one (1) replacement sheet. As amended, Figure 11 now includes reference numerals for two valve seats in the figure.

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STATUS OF CLAIMS

Claims 1-20 are presently pending in the application. Applicant has amended claim 5 to correct a typographical error. Figures 1-8 have been amended to include the label, PRIOR ART. Figure 11 has been amended to include reference numerals for the two valve seats in the figure. Applicant submits that no new matter has been added.

REMARKS

Informalities

In the Office Action, the Examiner states that Figures 1-8 should be designated by a legend such as —Prior Art—because only that which is old is illustrated. In addition, the Examiner objected to the drawings as failing to show every feature of the invention specified in the claims. Specifically, the Examiner states that the “two valve seats” of claims 1, 2, 5, 6, 11, 19, and 20 and the first position, second position and the default neutral position of the valve must be shown or the features canceled from the claims. The Examiner further states that the neutral position of the valve is not shown in Figure 11 nor does the specification include that figure 11 represents the neutral position of the valve.

In response to the Examiner's request to designate Figures 1-8 as prior art, Applicant respectfully traverses the Examiner's objections and disagrees with the Examiner's statement that Figure 1 contains “only that which is old.” Rather, as pointed out in Applicant's prior amendment to paragraph [0012] of the specification, Figure 1 illustrates a prior art stent apparatus that can be used with the new valves of the present invention. Thus, since the entirety of Figure 1 is not prior art, Applicant states that Figure 1 is not required to be labeled PRIOR ART.

However, to facilitate the prosecution of the present application, Applicant has amended Figures 1 through 8 to include the label, “PRIOR ART.” Applicant is submitting amended replacement drawing sheets including all of the figures appearing on the immediate prior version of the sheet and labeled in compliance with 37 C.F.R. 1.121(d).

The fact that Figure 1 contains an existing stent-spraying apparatus that contains valves of the present invention (which are not prior art) is clarified by Applicant's prior amendment of the description of Figure 1 in the Brief Description of the Drawings (paragraph [0012]) (see

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Applicant's October 10, 2006 Amendment and Response, wherein Applicant amended paragraph [0012] to state that "FIG 1 depicts an existing stent-spraying apparatus, which includes the exemplary embodiment of the dual pneumatic actuated three way valve illustrated in FIG 9, in accordance with an embodiment of the invention").

In the Office Action, the Examiner further objected to the drawings as failing to show every feature of the invention specified in the claims. Specifically, the Examiner requests Applicant to show "two valve seats, the first position, the second position, and the default neutral position of the valve" in the drawings or to cancel the features from the claims.

In response, Applicant states that the amended drawings are in compliance with 37 C.F.R. 1.83(a). The valve in the first position, second position, and default position are illustrated, for example, in FIGS. 17A, 17B, and 17C, respectively, in the form of a labeled representation in accordance with 37 C.F.R. 1.83(a). One of skill in the art would readily understand that the valve 1) can be pneumatically operated to open the first valve seat while closing the second valve seat, 2) can be pneumatically operated to close the first valve seat while opening the second valve seat, or 3) can occupy a central position where the first and second valve seats are open (the default neutral position) when supply pressure operating the valve is removed.

Regarding the Examiner's statement that the figures fail to disclose "two valve seats," Applicant has inserted reference numerals in the figures to point out the two valve seats that already occur in the drawings. Specifically, Applicant has amended Figure 11 and the specification to include the reference numerals 84a and 84b for the disclosed valve seats. Applicant states that the two valve seats are supported by the figures as filed and in the description and claims as originally filed and do not constitute new matter.

Rejection Under 35 U.S.C. §112, first paragraph

In the Office Action, the Examiner maintained his rejection of claims 2, 4, 11 and 19 under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. Specifically, the Examiner states that the "Examiner is unsure as to how the valve returns to its neutral state without the use of a spring return mechanism. If the valve is in a closed position, and the pneumatic forces are removed from both pneumatic ports simultaneously, how does the

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valve member move from the closed position to the open position without the use of a spring return mechanism?"

In response, Applicant respectfully traverses the rejection under 112, first paragraph and its accompanying remarks.

Applicant would like to clarify and to answer Examiner's question about how the valve returns to its neutral state without the use of a spring return mechanism. As an initial matter, Applicant draws the Examiner's attention to the default structure of Applicant's device in contrast to prior art three-way valves. In the Takasago three-way valve of Figures 2-8, due to the presence of the spring return in the valve (*see* Figure 5), there is *always an actuating force on the valve, even when the supply pressure operating the valve is removed, e.g., when the valve is not in use* (*see* paragraph [0002] of the Background and *see also* the October 10, 2006 Amendment and Response in which Applicant describes in great detail the mechanics of the Takasago valve with a spring return). In contrast, in the present invention, "all valve seats of the medical device [are] *open* when the unit is not in use." (paragraph [0005]) (emphasis added).

Referring to Figure 9, the three-way valve of the present invention has two ends, which remain open when the unit is not in use, i.e., unit is in a default neutral state. As described in the specification with respect to Figure 9, "[F]our millimeter tubing 71 connects to *one end* of the three-way valve, which is coupled to a nitrogen source for controlling the valve. Six millimeter tubing 74 connects to the *other end* of the three-way valve, which is also coupled to a nitrogen source for controlling the valve. According to one aspect of the present invention, when the nitrogen pressure is removed, a *default neutral state* is achieved in which *both valve seats of the three-way valve are open*, thereby preventing solids buildup or gluing of the valve seats closed by drying agents. Three valve ports are available 73, 75 and 76 for use to couple to a reservoir, a spray nozzle and syringe, or other applications requiring three valves." (emphasis added) (paragraph [0025]).

Turning now to the Examiner's question regarding "how the valve returns to its neutral state without the use of a spring return mechanism," Applicant states that the spring return mechanism is not necessary because Applicant's device contains a second pneumatic return. As shown in Figure 11, Applicant's device is structured so as "to make the valve 70 operate with a second pneumatic return rather than a spring return mechanism." Thus, where a spring return

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mechanism would normally be located, Applicant's device provides a second pneumatic return. Instead of the spring return mechanism, the device provides other structural elements that allow the device to still function without such spring return mechanism. This is achieved in Applicant's invention, for example, by adding the elements shown outside the "box" illustrated in Figure 11: "a plunger 77 is added along with an air pressure diaphragm 78, a modified valve bracket 30, and a 6-millimeter tubing interconnection 74." (paragraph [0032]). Because the valve is fully pneumatically driven, when the pneumatic force is removed from the valve (e.g., when the valve is not in use), the assembly of valve seats interlocked with a small ceramic stem is neither forced to the right nor to the left, allowing the assembly to return to its centered "equilibrium" position wherein both valve seats are open. A great advantage of having a device where the valve seats of the three-way valve are open in a default neutral state is that it prevents the possibility of the valve becoming glued shut by drying agents, which has been a problem in prior art valves wherein the valve seat is closed in its neutral state (paragraph [0025]).

Applicant reiterates that the claims are fully enabled and requests that the Examiner reconsider and withdraw his rejection.

Rejection Under 35 U.S.C. §103(a) – Kintner and acknowledged state of the art

Claims 2, 4, 5, 7, 10-13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the applicant's admitted prior art of Figure 1 in view of Kintner (U.S. Patent No. 3,426,799).

In response, Applicant respectfully traverses the rejection and its accompanying remarks. Applicant asserts that the Examiner has not satisfied his burden of establishing a *prima facie* case of obviousness based upon the prior art.

The Examiner asserts that applicant's admitted prior art of Figure 1 in combination with the valve of Kintner, teaches the claimed invention. Specifically, the Examiner asserts that while "the admitted prior art does not specifically disclose that the valve is a pneumatically actuated three-way valve with no spring return mechanism and two valve seats. However, Kintner shows a pneumatic actuated valve (figures 1 and 2) and a three-way valve (figure 3), both having no spring return mechanism....It would have been obvious to...substitute the new pneumatically actuated three-way valve of Kintner for the three-way valve of figure 1 in order to make the

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medical device operate more precisely by having a pneumatic return mechanism that can be adjusted."

The Examiner's primary argument appears to be that Figure 1 of Applicant's teaches all of the elements of the invention of independent claim 1 except that it fails to teach "that the valve is a pneumatically actuated three-way valve with no spring return mechanism and two valve seats." To remedy such deficiency, the Examiner then turns to Kintner, a 1969 patent document for an "Automatic Valve." However, Kintner fails as a primary reference. The valve of Kintner simply does not disclose a dual pneumatic actuated three-way valve comprising two air pressure diaphragms and two valve seats that is dual actuated with no spring return mechanism.

Upon reviewing the valve device of Kintner in detail, it becomes apparent why the device of Kintner fails to teach the claimed invention and why the combination with the acknowledged prior art fails to establish a *prima facie* case of obviousness. Kintner expressly *teaches away* from valves such as those of the present invention that include air pressure diaphragms and valve seats, dismissing them as undesirable. Instead of valves having seats and diaphragms, Kintner advocates a valve actuated by a "piston which can be moved by application of extremely small pressures to operate the valve" and which dispenses with the need for "costly stems, and unreliable seats and diaphragms." (col. 1, lines 7-15).

Entirely different in its mechanism from the valves of the present invention, the Kintner valve involves a sliding piston assembly that moves from a default closed "seated position" to an "open position." Specifically, Kintner teaches "floating O-rings" wrapped around a series of pistons that are mounted on piston rods. In its default state, as shown in Fig. 1 of Kintner, the valve is in the "closed position." (col. 1, lines 35-37). Then, "[i]n operation, the O-ring actually "floats" radially outwardly as it moves from the position shown in Fig. 1 to that shown in Fig. 2 since the stretched O-ring leaves its seating position during such movement as it slides across the recessed area 16 in the flow stream. Line pressures immediately encapsulate the O-ring." (col. 2, lines 48-66).

Thus, even if one of skill in the art were assumed to be motivated to combine Kintner with the acknowledged prior art, which he would not, the result would not be the present invention. There is nothing to support the assertion that the piston-valve of Kintner could result

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in the claimed three-way valve having "a default neutral state in which all valve seats of said three-way valve remain open when supply pressure operating said valve is removed." Without any type of force to move the piston, the valve of Kintner would remain in the closed position as discussed above. The Examiner has not shown otherwise.

Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in, KSR Int'l v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740-41, 82 USPQ 1385, 1396 (2007). Applicant respectfully states that the Examiner has neither met his burden of establishing a *prima facie* case of obviousness nor provided a rational underpinning to support his legal conclusion of obviousness.

As the Kintner reference, either singly or in combination with the acknowledged prior art, fails to establish a *prima facie* case of obviousness, reconsideration and withdrawal of the rejection as being unpatentable over the cited art, is therefore requested.

For at least these reasons, it is respectfully submitted that the rejected claims are patentable over the cited references.

CONCLUSION

Applicants respectfully submit that all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite the application at large, request is made that the Examiner telephone the undersigned attorney at (908) 518-7700, ext. 7 in order to resolve any outstanding issues.

FEES

The Office is authorized to charge any fees required to deposit account number 50-1047.

Respectfully submitted,



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